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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,247	01/14/2002	Adolfo Goren	P 0280702	1041

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EXAMINER	
HOFFMAN, SUSAN COE	
ART UNIT	PAPER NUMBER
1655	
MAIL DATE	DELIVERY MODE
07/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/076,247	GOREN ET AL.	
	Examiner	Art Unit	
	Susan Coe Hoffman	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *1-7,11,14-38,41 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-10,12,13,39,40 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on January 27, 2009 has been entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

2. Claims 1-43 are pending.

3. In the reply filed on May 18, 2005, applicant elected of Group II, now claims 8-13 and 39-43, *Allium cepa* for species A and rhinovirus for species B **without** traverse.

4. Claims 1-7, 11, 14-38, 41, and 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 18, 2005.

5. Claims 8-10, 12, 13, 39-40 and 43 are examined on the merits solely in regards to the elected species.

Claim Rejections - 35 USC § 103

6. Claims 8-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chinese Pat. Appl. No. 1089152 A (1994) - English translation provided.

CN '152 teaches a method for treating a cold (i.e. a rhinoviral infection) using an onion preparation. The reference teaches using an onion juice product that is produced by pressing,

concentrating, drying and grinding the onion to produce a granule or powder preparation (see claims 1 and 2).

While the reference does specifically teach that the onion can be powdered, it does not specifically teach that the powder particles have the size claimed by applicant. Applicant claims a wide range of sizes for the particles. Applicant's specification admits that these sizes include a powder that is about the size of talcum powder to a powder that is about the size of confectionary sugar (see paragraph 35 of the published application - US 2003/0026859). Thus, it seems very likely that the onion powder in the reference is of a size that would fall within applicant's claimed range. However, even if the powder produced using the method taught by the reference is not necessarily the size of applicant's powders, an artisan of ordinary skill would reasonably expect that powder size is a result effective parameter that could be optimized. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The reference teaches a range of particle sizes, from powder to granule. Thus, by suggesting a degree of particle sizes the reference acknowledges that particle size of the onion preparation can be varied. Therefore, an artisan would have been motivated to modify the particle sizes of the onion preparation in order to formulate a preparation that is best able to treat the cold virus.

In addition, the reference does not specifically teach that the granules and powders have the water content claimed by applicant. However, the reference does teach drying the onion juice during the production of the granules and powders. Furthermore, the water content would also be obvious to optimize because a person of ordinary skill in the art would recognize that a

high water content would make the granules and powders stick together. Thus, the water content is also a parameter that is considered within the prevue of routine optimization

The reference also does not specifically teach administering the onion in the amounts claimed by applicant. The dosage amount of a pharmaceutically active ingredient is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The reference teaches that the onion preparation is a pharmaceutically active ingredient useful for treating the cold virus. An artisan of ordinary skill would routinely determine and modify the optimal dosage amount of a pharmaceutically active ingredient based on the patient's age, weight, gender, and condition. Therefore, an artisan would have been motivated to modify the dosage amount of the onion preparation in order to formulate a product that best achieves the treatment of a cold as taught by the reference. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of dosage amount would have been obvious at the time of applicant's invention.

Response to Arguments

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not teach the claimed invention because the reference teaches using onion juice that is dried and ground to produce the powder rather than particulate, dehydrated plant material. However, the reference product is considered to meet applicant's limitation that the product is dehydrated, particulate plant material. The Random House dictionary defines "material" as "the substance or substances of which a thing is

made or composed" (http://dictionary.infoplease.com/material). Onion juice is clearly a substance that is part of the overall composition of the onion. Thus, onion juice is considered to be plant material. The reference teaches drying (i.e. dehydrating) and then grinding the dried juice into particulate form. Therefore, the reference teaches particulate, dehydrated plant material derived from onion.

Applicant also argues that CN '152 only teaches administering an extracted and distilled composition from onion. However, as discussed above, claim 2 of the reference clearly teaches using dehydrated, powdered onion juice. This onion juice has not been subjected to solvent extraction or distillation.

7. Claims 8-10, 12, 13, 39-40 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chinese Pat. Appl. No. 1089152 A (1994) in view of US Pat. No. 4,409,237.

As discussed above, CN ' 152 teaches a powdered composition comprising onion for treating the common cold. The reference does not specifically teach the particle sizes claimed in claims 13, 39, 40 or 43. However, the particle size of a pharmaceutical composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The optimization of particle size is taught in US '237. This reference teaches varying the particle size of an oral pharmaceutical to achieve the best drug absorption, drug distribution, and mouth-feel for the patient (see column 7). Thus, particle size of a drug is a known general condition that would be obvious for a person of ordinary skill in the art

to optimize. It would have been customary for an artisan of ordinary skill to determine the optimal particle size in order to best achieve the desired results of treating the common cold. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of particle size would have been obvious at the time of applicant's invention.

Response to Amendment

Applicant argues that US '237 does not cure the deficiencies of CN '152. However, CN '152 is not considered to be deficient for the reasons set forth above.

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Coe Hoffman/
Primary Examiner, Art Unit 1655